DETAILED ACTION

During an interview on December 11, 2008, applicants' representative pointed out that the examiner included claims in the rejections that were no longer pending and failed to address several limitations in the claims and requested further explanation. The examiner agreed to issue a supplemental office action to correct those errors and restart the period of response from the day of contact to enable applicant to respond fully.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-3, 5-8, 10-36, 38-43, 45-48, 50-75, 78-80, 119-131 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Independent claims 1 and 41 are ambiguous as to whether current is configured to lower heart rate variability below a baseline heart rate variability of the subject which ***corresponds*** to the heart rate variability when the current is not applied or whether the current drives the heart rate variability below a baseline when the current is turned off.

In addition the apparatus claims, particularly Claim 1 requires that the controller is configured to configure the current to reduce the heart rate variability below a baseline of the subject when the current is not applied. However, this would seem depend upon the subject's heart rate variability which is unknown to

the apparatus. There is no particular circuitry recited for feedback, determining threshold. or adjusting in the claim and thus it appears to be device for providing stimulating current. Only when a particular subject is selected and the device applied can one determine whether the device will perform a lowering the subject's heart rate variability, especially by the percentages recited in dependent claims. In claim 41, it is unclear if the "results" are an intended result or an actual result since applicant does not claim that the subject heart rate variable is altered, only that the current is configured to alter the heart rate variability.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-3, 5-8, 10-36, 38-43, 46-48, 50-51, 53-55, 57-66, 69-75, 78, 120-124, 126-131 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the

alternative, under 35 U.S.C. 103(a) as obvious over Osorio et al. USPN 6,341,236.

Applicant's newly added claim language for the apparatus claims 1-3, 5-8, 10-36, 38-40, 119-124 is directed to an intended use and the ability of the device's controller to provide a configured current to lower a heart rate variability. No particular electronics for detecting, analyzing or otherwise operating automatically based upon feedback, is recited or disclosed. In this regard the interpretation is whether the programmed stimulation in the controller is capable of performing such a heart rate variability lowering to a particular patient exhibiting such heart rate variability to which it is applied. In addition, applicant's method claims 41-42, 45-48, 50-75, 78-80, 125-131 are vague as to whether the method includes the patient's heart rate variability being lowered or whether the stimulation is configured to merely intend the results.

In this regard to claims 1 and 41, Osorio et al. teach a method of vagus stimulation which uses a control unit 200 which configures current to apply vagal simulation to treat epileptic seizures as well as control heart rate variability so as to reduce it when necessary. The examiner believes that the Osorio et al. device is capable of reducing heart rate variability in a patient that has a pre-existing high heart rate variable condition baseline condition if it were applied to such a person. For example, a patient that inherently has a variable heart rate greater than the results shown in figure 7 during the 37 sec stimulation trial could be treated with such stimulation to control the heart rate and provide a heart rate variability as shown. Thus the device is capable of performing the recited

function. In addition, the example shown in figure 7, which is applicable to applicant's method claim 41, seems to show vagal simulation that has reduced heart rate variablility during VNS as opposed to prior and after the stimulation. The heart rate seems to fluctuate less during the VNS sample provided by Osorio et al in the figure7. The examiner considers the recited structure and steps to be inherent or otherwise an obvious application of the Osorio et al device in using the device on subjects with higher heart rates.

Regarding claims 2-3,15-16, 31,34 -36, 42-43, 55, 71- 75, 78, 120-124, 126-131 the device, in the examiner's opinion, does not substantially reduce the heart rate in figure 7 and Osorio et al. teaches that a desired heart rate may be achieved (column 10) lines 42-53. In figure 7, the examiner considers the heart rate baseline to be 71 BPM and the heart rate variability baseline to be (84-71) 13 bpm prior to application of the stimulus. The heart rate drops to about 65 (about 10%) with a variability of [(72-65)/13] greater than 10 %. The heart rate can otherwise be controlled to achieve a desired heart rate which would include a normal range. (column 10 lines 42-53). Heart rate sensor 15 provides feedback (column 6 lines 8-10) for driving the stimulation as recited in claim 31. Figure 7 shows a lower target rate during stimulation. The device is capable of reducing a heart rate variability by 50% depending on the condition of the subject. (i.e. some experiencing flutter)

Regarding claims 5, 6, 7, 8, 13, 14, 46, 47, 48, 53-54 are statements of intended use. The Osorio et al device is capable of reducing heart rate variability in subjects who also happen to possess variability in the recited frequency

ranges as well as applying or not applying the driving current when the subject happens to be resting, exercising, sleeping or is awake. . No feedback mechanisms or input is required by the claims.

Regarding claims 10-11, 50, 61, figure 7 shows intermittent current application with breaks at g1 to g5 in a plurality of cycles and appears to be unsynchronized from the figure and no synchronization taught.

Regarding claim 12, the device is configured and capable of driving the electrode device responsive to a circadian rhythm eg. if the epileptic attacks in accordance a circadian rhythm.

Regarding claims 17-20, 57-60 the examiner considers the entire operating time to be a window and figure 7 demonstrates a window of 37 seconds. The device would last as long as the epileptic attack. Applicant's intended use statement provides no structural distinction in the apparatus claims and the reduction appears to be inherent to figure 7 or otherwise obvious as a desirable result.

With respect to claims 21-26, 29-30, 61-66, 69-70, Osorio et al teach that the vagus stimulation is in the form of pulses of.02-1.5 millisecond duration and at repetitions rates of 2-2500 Hz. One could separate out each pulse as a burst or non pulse (0) pulses based upon the definitions in claims 29-30 and if not inherently suggested, would be obvious to apply them in a plurality of cycles. When adjusting based upon a standard deviation or mean IHR (features of the cardiac signal) a delay would occur from the finished calculation to the time of stimulation.

Concerning claims 38, 39, 40, 120, the Osorio et al device performs the task of providing current to provide heart rate control and heart rate variability control. These functions make the device inherently be capable of treating the recited conditions if they were to arise during the treatment of a patient to treat the conditions of the patient to which they are applied since the they use similar teachniques.

Concerning claims 16, 27-28, 32-33, 51, the Osorio et al. timing is either synchronized to the heart or unsynchronized. One of which is anticipated, the other is obvious since it was well known to do both. The device can be started at any time and would be capable of being synchronized or unsynchronized and could be started anywhere in the cardiac cycle.

Claims 119 and 125 are rejected under 35 U.S.C. 103(a) as being unpatentable over Osorio et al USPN 6,341,236 in view of Stroetman et al USPN 5,578,061 (Traver et al "Clinical Experience with Helical Bipolar stimulating lead"). To have used a current strength of 2 to 10 milliamps in the Osorio et al device would have been obvious in view of Stroetman et al who discusses the Traver et al paper wherein such currents are used.

Claims 45, 52, 56, 67-68, 79-80 are rejected under 35 U.S.C. 103(a) as being unpatentable over Osorio et al. USPN 6,341,236 in view of Schroppel et al. USPN 6,571,121.To have applied the current treatment of Osorio et al. to reduce

heart rate variability during epochs of dangerous heart rate variability as described by Schroppel et al. would have been obvious.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-3, 5-8, 10-36, 38-43, 45-48, 50-75, 78-80, 86, 119-131 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schroeppel et al USPN 6,571,121 in view of Osorio et al. USPN 6,341,236.

Schroeppel teach a device to treat various stages of heart rate variability using a plurality of treatment regimens design to control the heart and notes an increase or decrease in heart rate variability may indicate the beginning of cardiac arrest. Such stimulation may be neural (vagus) or to the heart. Although not explicitly stated, it is believed the treatments will be halted one normal heart variability is achieved. Thus the examiner considers the Schroeppel device to teach the essence of the claim reverting to a statistically normal heart rate variablility is the goal of the device as in Osorio et al. The examiner includes Osorio et al for its explicit teaching of currents reducing heart rate variability. To have made the reduction of heart rate variability the goal of the Schroeppel

treatments and used the Osorio et al techniques would have been obvious. The teachings of Osorio are explained above. To have used these techniques with particular reference to figure 7, for vagus stimulation to reduce heart rate variability when detected during arrhythmia and episodes of increased heart rate variability out of the normal zones defined by Schroeppel would have been obvious.

Response to Arguments

Applicant's arguments filed 1-10-2008 have been fully considered but they are not persuasive. Claim 1 is directed to intended use as explained above and Claim 41 is considered to be shown by figure 7 with the Osorio et al disclosure still reading thereon. The examiner also considers the combined teachings of Schroeppel and Osorio et al to meet the claim language. Applicant does not provide and concrete examples of his work. The specification is largely written in a fashion making many suggestions as to how the device may be used but provides little detail to the specifics. In this regard, once a demonstration is provided that the use of vagal stimulation can be used to reduce heart rate variability (Osorio et al) as well as instances of where applicable (Schroeppel) the suggestions of use made by applicant become obvious variants.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mark W. Bockelman whose telephone number is (571) 272-4941. The examiner can normally be reached on Monday - Friday 8:00 - 4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Carl Layno can be reached on (571) 272 -4949. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Mark W Bockelman/
Primary Examiner, Art Unit 3766
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